Clinical Trial Protocol
Iranian Registry of Clinical Trials

23 Jun 2026

Comparison of the effectiveness of methotrexate and actinomycin D in the treatment of patients with C-section ectopic pregnancy

Protocol summary

Study aim
The aim of this study is to investigate and compare the effect of methotrexate and actinomycin D on patients with cesarean scar ectopic pregnancy, due to less side effects, more accessibility and less costs in the treatment by Actinomycin-D as a chemotherapy agent that has side effects similar to methotrexate without central nervous system's side effects.

Design
Two arm parallel group, double-blind, randomized, phase 3 clinical trial on 32 patients. Lottery method used for randomization.

Settings and conduct
Eligible patients who referred to Hazrat Rasool Akram and Firozgar Hospital in Tehran were assigned to two groups, the first group received methotrexate and the second group Actinomycin D. Then, BHCG levels are recorded. If there is any complication, drop in hemoglobin or no reduction in BHCG, the intervention will be discontinued and resection of the mass will be performed by surgical intervention.

Participants/Inclusion and exclusion criteria
32 patients with C-section ectopic pregnancy will enrolled. Patients with vaginal bleeding and hemodynamic unstability will be excluded.

Intervention groups
First group will receive actinomycin D and the second methotrexate.

Main outcome variables
level of the blood chorionic gonadotropin hormone (BHCG)

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20151020024625N16**
Registration date: **2023-04-04, 1402/01/15**
Registration timing: **prospective**

Last update: **2023-04-04, 1402/01/15**
Update count: **0**

Registration date
2023-04-04, 1402/01/15

Registrant information
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-05-05, 1402/02/15

Expected recruitment end date
2024-03-05, 1402/12/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effectiveness of methotrexate and actinomycin D in the treatment of patients with C-section ectopic pregnancy

Public title
Assessing the effectiveness of methotrexate and actinomycin D in the treatment of patients with C-section

ectopic pregnancy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Confirmed diagnosis of -section ectopic pregnancy

Exclusion criteria:

Gestational age more than 13 weeks at the time of diagnosis Heavy vaginal bleeding Hemodynamic changes

Age

No age limit

Gender

Female

Phase

3

Groups that have been masked

- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **32**

Randomization (investigator's opinion)

Randomized

Randomization description

For randomization, at first stage, 32 spheres from one to 32 are considered and following that will randomly divided into two equal parts, including "1" (Intervention1) and group 2 (Intervention2), and then using a lottery container, the ball of each group taken out and the intended sequence will be recorded.

Blinding (investigator's opinion)

Double blinded

Blinding description

The blinding of the study is such that the care provider, outcome assessor and biostatistician do not know the content of the intervention. For administration, the drug is drawn by the researcher into the syringe and given to the clinical care provider for administration by mentioning the administration method. The outcome assessor records the outcome based on the patient's identity number according to the randomization table, and the data collected based on the number and mention of the first and second intervention is provided to the biostatistician for analysis.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee, Iran University of Medical Sciences

Street address

Hemmat Expressway

City

Tehran

Province

Tehran

Postal code

۱۴۴۹۶۱۴۵۳۵

Approval date

2022-08-06, 1401/05/15

Ethics committee reference number

IR.IUMS.FMD.REC.1401.269

Health conditions studied

1

Description of health condition studied

C-Section Ectopic Pregnancy

ICD-10 code

O00.9

ICD-10 code description

Ectopic pregnancy, unspecified

Primary outcomes

1

Description

Level of the blood chorionic gonadotropin hormone (BHCG)

Timepoint

4, 7, 14 and 21 days after intervention

Method of measurement

Enzyme-Linked Immunesorbent Assay (ELIZA)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Methotrexate is given as a single dose of 50 mg by intramuscular injection. This dose is repeated after 14 days if there is no therapeutic result.

Category

Treatment - Drugs

2

Description

Intervention group: Actinomycin D is given as a single dose of 0.5 mg by intravenous infusion. This dose is repeated after 14 days if there is no therapeutic result.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Hazrat Rasool Akram hospital
Full name of responsible person
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2

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Schoolofmedicine@iums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Iran University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
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Full name of responsible person
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
The data collection will be presented anonymously.
When the data will become available and for how long
After publishing of the results, the data will be delivered upon request and after verification.
To whom data/document is available
The data will be available only for academic researchers.
Under which criteria data/document could be used
In order to conduct similar studies.
From where data/document is obtainable
Direct request from the scientific responsible.
What processes are involved for a request to access data/document
After request and authentication, the data will be provided.
Comments